



Food and Drug Administration Minneapolis District 240 Hennepin Avenue Minneapolis MN 55401-1999 Telephone: 612-334-4100

March 6, 2002

WARNING LETTER

CERTIFIED MAIL RETURN RECEIPT REQUESTED

Refer to MIN 02 - 28

Loren A. Duescher Co-owner Duescher Hilltop Jerseys E3470 Highway F Kewaunee, Wisconsin 54216

Dear Mr. Duescher:

An investigation at your dairy farm conducted by our investigator on January 23-24, 30 and February 13, 2002, revealed that you have caused animal drugs to become adulterated within the meaning of Section 501(a)(5) of the Federal Food, Drug, and Cosmetic Act (the Act).

On or about December 10, 2001, you sold a dairy cow identified with back tag number 35DK3982 for slaughter as human food to U.S. Department of Agriculture (USDA) analysis of tissue samples collected from this cow identified the presence of neomycin at 32.38 ppm in the kidney. A tolerance of 7.2 ppm has been established for residues in the edible tissue of cattle (Title 21, Code of Federal Regulations, Part 556.430).

You are adulterating brand of neomycin sulfate that your firm administers to dairy cattle within the meaning of Section 501(a)(5) when you fail to use the drug in conformance with its approved labeling. Your administration of neomycin sulfate to dairy cattle either at higher than labeled dosages or without following the labeled withdrawal period causes the drug to be unsafe to use.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for ensuring that your overall operation and the foods you distribute are in compliance with the law. You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

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It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you adulterated a drug that had been shipped in interstate commerce is sufficient to hold you responsible for a violation of the Act.

Please notify this office in writing within 15 working days of the steps you have taken to bring your firm into compliance with the law. Your response should include each step being taken, that has been taken, or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to Compliance officer Timothy G. Philips at the above address.

Sincerely

James A. Rahto

Director

Minneapolis District

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